REMARKS

I. Status of the Claims/Amendments

Claims 1 through 4 and 7 through 15 have been withdrawn.

Claim 5 has been amended.

Claims 5 and 6 are pending in the present application.

Favorable reconsideration of this application as presently amended is respectfully requested. In this Amendment, claims 5 and 6 are amended. The amendment to claim 5 is supported, *inter alia*, in the Specification at page 16, lines 24-29, as well as in the language of claim 5 itself (preamble, "pathological feeding behavior"). No new matter has been added.

II. Interview with Examiner Chandra

Applicant's representative thanks the Examiner for the courtesies extended during a November 6, 2006, telephone interview with Examiner Chandra and Supervisory Examiner Eileen O'Hara. A copy of the Interview Summary Record is attached hereto as Exhibit A. The outstanding rejection(s) were discussed. Applicant's separate record of the substance of the interview is contained in the comments below.

During the interview, the distinction was made between the claimed methods for treating feeding behaviors in animals having a pathological condition, such as cachexia, and treating feeding behaviors in animal without a pathological condition, such as in the art cited, particularly in the cited reference of Cone *et al.* (feeding behavior in an animal without cachexia). This distinction was considered significant, and the Examiner stated that such would be further considered if presented together with references in support of the premise that observations on the feeding behaviors in animals without a pathological condition would not be considered instructive of treating feeding behaviors in animal having a pathological condition, such as cachexia.

Applicant supplies herewith a reference, Marks *et al.* (2001), Cancer Research, 61:1432-1438, in support of the distinction between treatments for animals without a

pathological condition, and animals with a pathological condition. This reference supports the premise forwarded during the interview in distinguishing the teachings of Cone *et al.*, from the presently claimed invention. This distinction in view of the reference now presented is discussed in greater detail below.

III. Rejection under 35 U.S.C. § 102(e) - Cone *et al.* (U.S. 6,1000,048)

Claims 5 and 6 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,100,048 to Cone, *et al.* (Cone). This rejection is respectfully traversed with respect to the claims as currently presented.

The '048 patent relates to melanocortin receptors, and methods of using these receptors in a screening assay to identify compounds that bind these receptors. Compounds within a pool of unknown compounds passed through the screening assay that bind these receptors are then proposed for use in the treatment of feeding behaviors in animal without any known pathology.

The '048 patent does not disclose a method for treating feeding behaviors in an animal having a clinical pathology, such as cachexia. More specifically, the compounds that are selected using the '048 patented screening method would not be expected to provide a compound that would be useful in treating cachexia because, *inter alia*,, these pathological conditions result in changes in the basal metabolism in the animal, lean muscle mass wasting, and melanocortin receptor activity/binding.

The attached journal article, Marks *et al.* (2001) (Cancer Research, 61:1432-1438), describes this distinction. At page 1435 of that reference, it is stated, "Under normal circumstances, animals and humans respond to starvation with a complex neuroendocrine response that ultimately leads to an *increase in appetite*, a relative *sparing of lean body mass* and burning of fat stores, and an overall *decrease in basal metabolic rate.* In contrast, cachexia refers to a *pathological state* of malnutrition wherein *appetite is diminished* concomitant with an *increase in metabolic rate* and a relative *wasting of lean body mass.* This combination is found in a number of disorders including cancer, cystic fibrosis, AIDS, rheumatoid arthritis and renal failure." The reference goes on to state:

> "numerous previous studies have demonstrated that cytokines released during inflammation and malignancy act on the CNS to alter the release and function of a number of key neurotransmitters, thereby altering

> both appetite and metabolic rate. . . Previous pharmacological studies have demonstrated an acute and chronic effect of central *melanocortin peptides* on feeding behavior and energy expenditure that parallels the *alterations* observed during the development of *cachexia*. The data presented here provide evidence that the hypothalamic *MC4-R* plays an integrative role in regulating the response to different cachexic stimuli and suggest that blockade of this receptor may ameliorate the *pathological metabolic state* observed in a number of diseases."

This passage, among others in this reference, clearly supports the premise upon which a distinction may be drawn between preventing or treating *normal* feeding behaviors in animals in a *non-pathological* metabolic state (no pathology), as compared to preventing or treating *pathological* feeding behaviors in animals in a *pathological metabolic state*, such as is observed in cachexia. In addition, the integrative role that hypothalamic MC4-R is observed in this reference to play in regulating the response of an afflicted animal to *cachexic stimuli*, provides even further evidence of the lack of any similarity between the treatment methods presented here with mammalian melanocortin MC-4 receptor antagonist for afflicted animals with a pathological feeding behavior, and other approaches that are appropriate for non-afflicted animals without any modification in basal metabolic state.

For the above reasons, and among others, Applicant respectfully requests that the rejection be withdrawn, and that the claims as now even more clearly defined, be passed to issue.

IV. Rejection under 35 U.S.C. § 102(e) - Dooley *et al.* (U.S. 6,350,430)

Claims 5 and 6 are rejected under 5 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,350,430 to Dooley, *et al.* ('430 patent). This rejection is respectfully traversed with respect to the claims as currently presented.

During the Examiner's Interview, the Dooley reference was not considered pertinent to the specific claimed subject matter. Specifically, the '430 patent does not relate to any pathological feeding behavior, and does not provide any teaching at all concerning the role of melaocortin receptors or ligands thereon in an animal having a pathological feeding behavior, such as cachexia. Instead, the patent relates to melanocortin receptor ligands and methods for assaying for melanocortin receptors in normal tissues obtained from animals without any associated pathology.

Withdrawal of the rejection of claims 5 and 6 over the '430 patent is respectfully requested.

V. Conclusion

If the Examiner has any questions or concerns regarding the present response, the Examiner is invited to contact Denise L. Mayfield at 703-563-2003.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance, and favorable action is respectfully solicited.

Respectfully submitted,

Denise L. Mayfield
Reg. No. 33,732
Customer No. 22,506

JAGTIANI + GUTTAG
Democracy Square Business Center
10363-A Democracy Lane
Fairfax, Virginia 22030
703-591-2664

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